

REMARKS

Claims 1-33 are now pending in the application. Claims 7, 9, 16, 17, and 21-27 have been withdrawn. 1, 6, 11, 13, and 15 have been amended. Claims 28-33 have been submitted for substantive examination. The basis for the foregoing amendments may be found throughout the written description, drawings, and claims as originally filed. The Examiner is respectfully requested to reconsider and withdraw the rejection(s) in view of the amendments and remarks contained herein.

DOUBLE PATENTING

Claims 1-6, 8, 10-15 and 18-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-24 of U.S. Patent No. 6,685,707. Applicants acknowledge this double patenting rejection and will submit a terminal disclaimer upon allowance of the subject application.

REJECTION UNDER 35 U.S.C. § 112

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicants regard as the invention. Claim 11 recites the limitation "the adjacent members" in lines 2 and 3. This rejection is respectfully traversed. Applicants have amended claim 11 to clarify that rotation of the cap is inhibited "relative to one of the bone plate and cranium". Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-6, 8, 10 and 12-15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,814,046 (Hopf). This rejection is respectfully traversed.

At the outset, Applicants note that claim 1 has been amended to recite that the post defines "threads that receive a mating portion of the cap". Claim 1 has also been amended to recite that the cap and base are fastened relative to one another to "secure at least one of the bone plate and the cranium between the cap and the base".

Applicants submit that Hopf fails to teach securing a bone plate or cranium between a cap and base. FIG. 3 of Hopf has been reproduced immediately below. Hopf discloses a spinal screw 1 having a first threaded part 9 and a second threaded part 11. The spinal screw cooperates with an L-shaped connection element 3. A shoulder 16 is defined at a run-out of the first threaded part 9. The shoulder 16 bears against a planar surface of the element 3. A nut 23 is used to clamp the connection part 3 against the shoulder 16. A distal end 12 of the screw 1 defines flats for gripping by a tool.

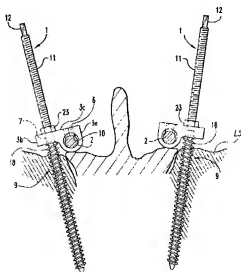


Fig. 3

The spinal screw arrangement of Hopf does not provide an assembly that includes a cap that fastens relative to a base to secure one of a bone plate and cranium between the cap and the base. Instead, the nut 23 is advanced to bear directly against the connecting member 3 (see FIG. 3 above).

The Office Action further states that Hopf discloses “a torque-limiting section (where 12 turns to 11) inherently preventing a level of over-tightening of the cap relative to the base”. Applicants submit that feature 12 is not a torque-limiting feature. Hopf specifically discloses an entirely different strategy to avoid over-tightening. In this regard, the surgeon is warned when to stop advancing the screw when the screw thread length corresponds to the length of the passage through the vertebra. Specifically, when the surgeon must suddenly exert a higher torque, he must stop his screwing effort. See e.g. Col. 5, Lines 2-12. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 8, 10-12 and 18-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,068,631 (Lerch). This rejection is respectfully traversed. FIGS. 6 and 7 of Lerch have been reproduced immediately below. Lerch discloses a cranial clamp having a pin 11 and two disks 21 and 22. As shown in FIG. 7 a notch 112c can be formed in the shaft 112 that engages the outer surface of the second disc 22 and forces it towards the head 111 of the pin. The Office Action states that Lerch discloses a “torque limiting feature (deep indent between ribs 112c)”. Applicants submit that the indent 112c cannot be interpreted as a torque-limiting feature. As set forth above and described in detail at Col. 4, Lines 4-8, the indent or notch 112c is used to force the disc 22 toward the head 111 of the pin. Applicants further submit that while

Lerch discloses a threaded portion 112a in another embodiment (FIG. 8), threads cannot be compatible with the notched shaft 112 of FIG. 7. Rather, Lerch describes the notch as an alternative to threads for urging disc 22 toward the head 111 of the pin. Assuming *arguendo*, that notch 112c can be interpreted as a torque-limiting feature, Lerch does not show how the notch 112c can be compatible with a threaded post to allow a cap to advance along the threads and beyond the notch 112c. Explained further, the notch 112c would preclude advancement of the second disk an axial distance beyond the notch 112c. The instant disclosure as claimed recites a post defining threads that receive a corresponding mating portion of the cap and further defines a torque-limiting feature. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

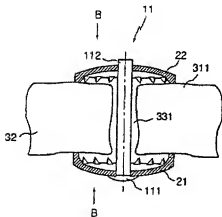


Figure 6

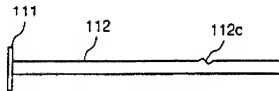


Figure 7

REJECTION UNDER 35 U.S.C. § 103

Claims 1-6, 8, 10-15 and 18-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,585,739 (Kuras) in view of U.S. Pat. No. 6,022,351 (Bremer). Claims 18-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hopf. This rejection is respectfully traversed.

Kuras discloses an attachment device 40 including first and second wedge shaped members 42 and 44 connected by a shaft 46. The Office Action states that Kuras is silent of a torque-limiting feature. The Office Action states that Bremer teaches a post element having "at least one weakened section of significantly less thickness to prevent over tightening thereby preventing ratchet teeth from breaking". The fastener element 10 of Bremmer however has "a construction that is similar to that of a conventional plastic cable tie, with each ratchet tooth having a ramp surface 15" (Col. 4, Lines 12-14). A disk shaped locking element 11 defines an elongate opening 25 for receiving the plastic cable tie. Applicants submit that the cable tie construction of Kuras cannot define a "torque-limiting feature" because there is no "torque" being applied to the cable tie. Instead, it is a simple linear advancement of the distal end of the cable tie through the elongate opening 25 of the element 11. In sum, Applicants submit that the combination of Hopf and Kuras would not render obvious to one skilled in the art, the claims as amended herein.

NEW CLAIMS 28-33

Applicants have submitted new claims 28-33 for substantive examination. Applicants submit that these claims are not taught or rendered obvious by the cited art of record.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: June 14, 2007

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